

**Docket No.: TJU0001-107  
PATENT**

**Serial No.: 10/621,684  
Filed: July 17, 2003**

# **REMARKS**

## **Status of the Claims**

Claims 23-28, 30-34, 36 and 38-47 were in the application when the final rejection dated February 2, 2006 was mailed.

By way of the Amendment and Response filed on April 7, 2006 pursuant to 37 C.F.R. 1.116, claim 24 was canceled and claims 23 and 42 were amended.

Upon filing the instant Request for Continued Examination, Applicant requests that the Amendment and Response filed on April 7, 2006 be entered.

Upon entry of the Amendment and Response filed April 7, 2006, claims 23, 25-28, 30-34, 36 and 38-47 will be pending.

By way of this Amendment, claims 23 and 42 have been amended and new claims 48-56 have been added.

Upon entry of this Amendment, claims 23, 25-28, 30-34, 36 and 38-56 will be pending.

## **Summary of the Amendment**

Claims 23 and 42 have been amended to include peptides, antibodies and fragments thereof. Support for this amendment is found throughout the specification such as on page 18. No new matter has been added.

Claim 23 is also amended to recite that the active agent is a therapeutic agent. Support for this amendment is found throughout the specification such as on page 7. No new matter has been added.

New claims 48 refers specifically to unconjugated compositions that comprise an ST binding ligand and an active agent. New claims 49-56 refer to specific embodiments of the invention as set forth in new claim 48. Support for this amendment is found throughout the specification such as on pages 42-46. No new matter has been added.

The claims as amended and new claims all read on the elected invention and species.

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#### **Non-Rejected Claims**

In the Office Action dated February 2, 2006, the Office Action Summary indicated that each of pending 23-28, 30-34, 36 and 38-47 were rejected and that the rejection was final. The Detailed Action section indicated that 1) claims 23, 28, 30-31 and 41-42 were rejected under 35 U.S.C. §112, first paragraph; 2) claims 23-28 and 41-42 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 5,962,220; 3) claims 23-28 and 41-42 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,060,037; 4) claims 23-28 and 41-42 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 6,087,109; and claims 23-25, 28-32, 35-36 and 41-42 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 6, 8, 10, 32, 37, 9, 41-42, 54-55, 58, 63-64, 92, 96-97, 99, 102, 108, 109, 114, 116, 118-119, 125-153 of co-pending Application No. 08/468,449.

There are no rejections of claims 33, 34, 38, 39, 40 and 43-47. Accordingly, clarification or an indication that claims 33, 34, 38, 39, 40 and 43-47 are allowable is hereby respectfully requested.

#### **Rejection under 35 U.S.C. §112, first paragraph**

The Advisory Action indicates that the Amendment and Response filed April 7, 2006 overcomes the rejection of "Claims 23, 28, 31, 31, 41 and 42" under 35 U.S.C. §112, first paragraph, (written description requirement).

The Advisory Action contained what is presumably a typographical error and was intended to indicate that the Amendment and Response filed April 7, 2006 overcomes the rejection of Claims 23, 28, 30, 31, 41 and 42 under 35 U.S.C. 112, first paragraph, (written description requirement).

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In the Amendment and Response filed April 7, 2006, the term "ST receptor binding ligand" was amended to recite "ST receptor binding peptide."

Applicant has further amended claims 23 and 42 to enlarge the scope of the ST receptor ligand to refer to a peptide, an antibody and fragments thereof. Claims 23 and 42 as amended remain in compliance with the written description requirement.

Applicant respectfully requests that the rejection of claims 23, 28, 30, 31, 41 and 42 under 35 U.S.C. §112, first paragraph, be withdrawn.

#### **Double Patenting Rejections**

As noted in the Amendment and Response filed April 7, 2006, Applicant will file appropriate terminal disclaimers upon indication that claims would be otherwise allowable.

With respect to the rejection of claims 23-25, 28-32, 35-36, 41-42 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 6, 8, 10, 32, 37, 9, 41-42, 54-55, 58, 63-64, 92, 96-97, 99, 102, 108, 109, 114, 116, 118-119, 125-153 of co-pending Application No. 08/468,449, this rejection is provisional.

Claims 23-28 and 41-42 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 5,962,220.

Claims 23-28 and 41-42 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,087,109.

Claims 23-28 and 41-42 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,060,037.

Applicant respectfully urges that the rejection of claims 23-28 and 41-42 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,060,037 is improper and respectfully requests reconsideration. In order to properly reject claims under the judicially created doctrine of

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obviousness-type double patenting, the claims of the issued patent must, alone or in combination with other references, render the pending claim obvious. No case for obviousness has been made out.

Claims 1 and 2 of U.S. Patent No. 6,060,037, which refer to methods of radioimaging metastasized colorectal cancer cells, correspond non-elected Group IV of the instant application.

Claims 3 and 4 of U.S. Patent No. 6,060,037 refer to in vitro methods of screening individual for metastasized colorectal cancer.

Claim 5 of U.S. Patent No. 6,060,037 refers to in vitro methods of determining whether a tumor cell is a colorectal tumor cell.

Claims 6 and 7 of U.S. Patent No. 6,060,037, which refer to methods of treating individuals suspected of suffering from metastasized colorectal cancer, correspond to non-elected Groups II and V of the instant application.

Claim 8 of U.S. Patent No. 6,060,037, which refers to methods of treating individuals suspected of suffering from metastasized colorectal cancer, correspond to non-elected Group VI and of the instant application.

Claim 9 of U.S. Patent No. 6,060,037, which refers to methods of delivering a nucleic acid molecule to a cell that expresses ST receptors in an individual, corresponds to non-elected Group VII of the instant application.

Claim 10 of U.S. Patent No. 6,060,037 refer to kits for determining whether a sample contains a colorectal cancer cell.

Thus, each of claims 1, 2 and 6-9 of U.S. Patent No. 6,060,037 refer to subject matter which is patentably distinct from the subject matter of the claims in the instant application. The restriction requirement in the instant application, which was set forth in the Official Action dated October 1, 2004, makes clear that the subject matter of claims 1, 2 and 6-9 of U.S. Patent No. 6,060,037 represent separate and patentably distinct inventions from those of the elected invention as set forth in the pending claims. The restriction requirement makes clear that the subject matter of the cited claims in each instance was that of a separate and

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patentably distinct invention. A finding that the claims are obvious in view of the cited claims is completely contrary and inconsistent with the position taken by the Office in requiring restriction.

With respect to claims 3-5 and 10 of U.S. Patent No. 6,060,037, these claims do not teach or suggest the claimed invention. The presently claimed invention encompasses compositions of matter. Claims 3-5 and 10 of U.S. Patent No. 6,060,037 are directed to diagnostic methods and kits which neither teach nor suggest compositions which are the subject matter of the instant claims. The methods and kits in claims 3-5 and 10 of U.S. Patent No. 6,060,037 do not use or suggest the compositions which are the subject matter of the instant claims. The claims in the instant application do not define an invention that is merely an obvious variation of an invention claimed in U.S. Patent No. 6,060,037. Accordingly, the obviousness-type double patenting rejection is improper. Contrary to what is required under the law, no basis for rejection of the instant claims analogous to the analysis performed under a 35 U.S.C. §103 obviousness determination has been provided. In the absence of such an analysis, Applicant respectfully requests withdrawal of the rejection of claims 23-28 and 41-42 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,060,037.

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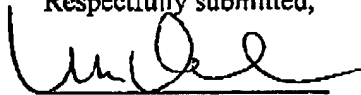
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**Conclusion**

Claims 23, 25-28, 30-34, 36 and 38-56 are in allowable form. An indication of allowability is therefore earnestly solicited. Applicant invites the Examiner to contact the undersigned at 215-665-5592 to clarify any unresolved issues raised by this response.

As indicated on the transmittal accompanying this response, the Commissioner is hereby authorized to charge any debit or credit any overpayment to Deposit Account No. 50-1275.

Respectfully submitted,



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